



ECSi

"Your Regulatory Compliance Expert"

May 17, 2018

Mr. Raju Patel
Senior Manager, Dangerous Goods and Environmental Programs
ABBOTT VASCULAR
26531 Ynez Road
Temecula, California 92591

**Subject: RESULTS OF ANNUAL ETHYLENE OXIDE SOURCE TESTING AND LEAK TESTING
PERFORMED AT ABBOTT VASCULAR IN TEMECULA, CALIFORNIA**

Dear Mr. Patel:

Please find attached a presentation of the results of the ethylene oxide source testing and leak testing performed at your facility by ECSi, on Thursday, May 17, 2018. These test results are to be kept with all records pertaining to SCAQMD-required testing of the EtO gas-sterilization system, and are to be made available upon request by the SCAQMD. A copy of all raw test data, complete with sample chromatograms and calibration data, will be maintained in our files, and will be made available upon request.

The test results indicate that you continue to operate your EtO sterilization and emission-control system (SCAQMD Permit Numbers F83295 and F83299) in compliance with SCAQMD Rule 1405. I will follow up with you in approximately five months to let you know when your next semi-annual leak test is due, and in approximately eleven months to let you know when your next annual source test/leak test is due.

The annual ethylene oxide emissions reported in Table 2 can be used for your facility's annual SCAQMD emissions report. If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer
ECSi

TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE (ABATOR #2 - F83299)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 17, 2018

<u>CYCLE PHASE</u>	<u>INJECTION TIME</u>	<u>INLET ETO CONC. (PPM)(1)</u>	<u>OUTLET ETO CONC. (PPM)(2)</u>	<u>ETO CONTROL EFFICIENCY</u>
Exhaust(3)	1106	712	0.01	99.9986
Exhaust	1109	2570	0.01	99.9996
Exhaust	1112	2570	0.01	99.9996
Exhaust	1115	4080	0.01	99.9998
Exhaust	1118	1050	0.01	99.9990
Exhaust	1121	4370	0.01	99.9998
Exhaust	1124	1940	0.01	99.9995
Exhaust	1127	906	0.01	99.9989
Exhaust	1130	1350	0.01	99.9993
Exhaust	1133	<u>8.48</u>	<u>0.01</u>	<u>99.8821</u>
TIME-WEIGHTED AVERAGE:		1956	0.0100	99.9876
Aeration	1136	155	0.01	99.9935
Aeration	1139	<u>2.91</u>	<u>0.01</u>	<u>99.6564</u>
TIME-WEIGHTED AVERAGE:		78.96	0.0100	99.8250
TIME-WEIGHTED AVERAGE CONTROL EFFICIENCY:				99.9605
SCAQMD REQUIRED CONTROL EFFICIENCY:				99.0

Notes:

(1) - PPM = parts per million by volume

(2) - 0.01 ppm is the quantification limit for the detector used at the outlet.

(3) - The exhaust phase started at 11:04, ended at 11:35.

(4) - The aeration phase started at 11:35, the first chamber evacuation was tested.

TABLE 2
ETHYLENE OXIDE MASS EMISSIONS
FROM A GAS STERILIZATION AND EMISSION CONTROL SYSTEM (F83299/F83295)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 17, 2018

<u>CYCLE PHASE</u>	<u>STACK FLOW(1)</u>	<u>OUTLET ETO MASS FLOW(2)</u>	<u>MINUTES/ CYCLE</u>	<u>CYCLES/ YEAR</u>	<u>ANNUAL ETO MASS EMISSIONS(3)</u>
Exhaust	48.2 DSCFM	0.00000006 lbs/min	31	60	0.0001 lbs/year
Aeration	48.2 DSCFM	0.00000006 lbs/min	6	60	0.00002 lbs/year
TOTAL ANNUAL ETO MASS EMISSIONS					0.0001 lbs/year

Notes:

(1) - DSCFM = Dry Standard Cubic Feet per Minute

(2) - lbs/min = pounds per minute

(3) - lbs/year = pounds per year

TABLE 3
ETHYLENE OXIDE LEAK TESTING
OF A GAS STERILIZATION SYSTEM (F83295)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 17, 2018

<u>COMPONENT GROUP TESTED</u>	<u>LEAKING COMPONENTS FOUND</u>	<u>CONCENTRATION</u>
Gas Cartridge / Injector	None	<1.0 ppm (1)
Sterilizer Inlet / Inbleed Valve	None	<1.0 ppm
Door Seal	None	<1.0 ppm
Sterilizer Outlet / Chamber Drain	None	<1.0 ppm
Venturi System / Filter	None	<1.0 ppm
Emission Control Device Inlet	None	<1.0 ppm

Notes:

(1) - PPM = parts per million by volume

Abator #2 (F83299) - Sterilizer #2 (F83295)

<u>DeltaP</u>	<u>SqRtDeltaP</u>	<u>Temp (F)</u>	<u>ppm EtO</u>	<u>stack ID =</u>	<u>3</u>	<u>in.</u>
				<u>stack area =</u>	<u>0.049</u>	<u>sq. in.</u>
				<u>press =</u>	<u>28.80</u>	<u>in. Hg</u>
				<u>Tstd =</u>	<u>528</u>	<u>deg R</u>
				<u>Pstd =</u>	<u>29.92</u>	<u>in Hg</u>
				<u>Cp =</u>	<u>0.99</u>	
				<u>Kp =</u>	<u>85.49</u>	
				<u>Velocity =</u>	<u>28.90</u>	<u>ft/sec</u>
				<u>Flow =</u>	<u>48.2</u>	<u>dscfm</u>
				<u>MWeto =</u>	<u>44.05</u>	
				<u>MolVol =</u>	<u>385.32</u>	
				<u>ppmv/ft3 =</u>	<u>1000000</u>	
				<u>EtO Mass Flow (Exh) =</u>	<u>0.00000006</u>	<u>lbs/min</u>
				<u>min/cycle =</u>	<u>31</u>	
				<u>cycles/year =</u>	<u>60</u>	
				<u>EtO Emissions (Exh) =</u>	<u>0.0001</u>	<u>lbs/year</u>
				<u>EtO Mass Flow (Aer) =</u>	<u>0.00000006</u>	<u>lbs/min</u>
				<u>min/cycle =</u>	<u>6</u>	
				<u>cycles/year =</u>	<u>60</u>	
				<u>EtO Emissions (Aer) =</u>	<u>0.00002</u>	<u>lbs/year</u>
				<u>Total EtO Emissions =</u>	<u>0.0001</u>	<u>lbs/year</u>